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The present invention is directed to a drug delivery conformal film applied to an implantable medical device. The drug delivery conformal film comprises a composition that is in vivo biocompatible and biodegradable or bio-erodable or bio-inert. An implantable medical device is coated with the drug delivery conformal film immediately prior to placement in the body. When the film-coated device is introduced into the body, the drug contained in the film coating is released in a local region. The invention provides a point of use in vivo drug delivery system whereby the drug and its concentration can be selected by medical personnel immediately prior to implantation of the medical device.

The status of the claims is as follows:

Claim 12 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite.

Claims 1, 5-6, 8 and 12-15 are rejected under 35 U.S.C. §102(b) as being anticipated by Sahatjian et al.

Claims 2-4, 9-12 and 16-20 are rejected under 35 U.S.C. §103(a) as being unpatentable over Sahatjian et al. in view of Desai et al.

Claims 7 and 8 are rejected under 35 U.S.C. §103(a) as being unpatentable over Sahatjian et al. in view of Loomis.

Claim 12 has been amended to address the terminology objected to by the Examiner. While original claim 12 is believed to provide proper support for this amendment, attention is also directed to the specification at page 5, lines 23-25 and page 9, lines 18-20.

The rejection of claims 1, 5-6, 8 and 12-15 under 35 U.S.C. §102(b) as being anticipated by Sahatjian et al. is respectfully traversed. Sahatjian et al. teach a stent coated with a drug-containing hydrogel. The drug is released from the hydrogel by pressure when the stent is expanded by an expandable balloon which causes the drug to be expressed from the hydrogel by mechanical action (expansion of the balloon and stent). However, there is no teaching that the hydrogel coating on the implanted device is in vivo biodegradable, bioabsorbable or bioerodable. The implanted device of Sahatjian et al. does not depend on the in vivo biodegradability, bioabsorbability or bioerodability for release of a drug but instead is limited to a device that experiences a change in dimension by mechanical means after positioning in order to release the drug.

Since the device of Sahatjian et al. is not concerned with the in vivo biodegradability, bioabsorbability or bioerodability for release of a drug coated on an implantable device, the rejection of claims 1, 5-6, 8 and 12-15 as being anticipated by Sahatjian et al. is improper and should be withdrawn.

Claims 2-4, 9-12 and 16-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian et al. in view of Desai et al. This rejection is respectfully traversed.

Sahatjian et al. is discussed above. Desai et al. teach a dual cross linked system comprising an ionically cross linked component and a covalently cross linked component. For the sake of argument, even if the coatings of Desai et al. were to be utilized by Sahatjian et al. (if such motivation existed), how would the coatings of Desai et al. perform given that Sahatjian et al. disclose squeezing the drug from the coating?

Desai et al. fails to properly add elements to the disclosure of Sahatjian et al. that render the present claims unpatentable for reasons of obviousness. As such, the

rejection of claims 2-4, 9-12, and 16-20 as being unpatentable over Sahatjian et al. in view of Desai et al. is improper and should be withdrawn.

Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sahatjian et al. in view of Loomis.

Sahatjian et al. is discussed above. Loomis teaches a coating comprising a water-insoluble copolymer having a bioresorbable region. Again, where is the guidance or motivation to look to Loomis to provide any alleged deficient subject matter in Sahatjian et al.? Even if such motivation were to exist (which it does not) and the teachings were properly combined, what would result? One can see little more than a coated medical device comprising water-insoluble co-polymer having a bioresorbable region in which any drug contained in the coating would be expelled under an applied pressure. This is not Applicants' claimed invention.

There is no water-insoluble copolymer/bioresorbable region structure as taught by Loomis in the present invention as the entire film coating is in vivo biocompatible and biodegradable or bioabsorbable or bioerodable.

For the reasons stated above, the rejection of claims 7 and 18 as being unpatentable over Sahatjian et al. in view of Loomis is improper and should be withdrawn.

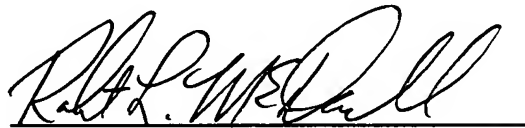
With the above amendments and remarks, the clarity of claim 12 has been addressed and prior art rejections are believed to be shown improper and should be immediately withdrawn. A prompt Notice of Allowance with respect to claims 1-20 is respectfully and earnestly solicited.

Having addressed all aspects of the Official Action, Applicants believe this response to be complete. However, if the Examiner feels the present response to be incomplete in any way, he is invited to contact Applicants' Agent at (585) 872-3857 to resolve any remaining issues.

Respectfully submitted,

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by



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